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| 09/804,369      | 03/12/2001  | Bastiaan Driehuys    | 5770-21             | 9041             |

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT PAPER NUMBER

1616

DATE MAILED: 08/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/804,369

Applicant(s)

DRIEHUYS ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 24-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that some of the grouped inventions should be rejoined because they share the same technical feature and/or are sufficiently related as to not constitute an undue burden on the examiner to search. This is not found persuasive because the grouped inventions have different or diverse methods steps which relate to unrelated inventions due to their different modes of operation, functions and effects. For example, the Group II invention is not limited to pulmonary embolism and only relates to a method of enhancing MRI-based medical images. This method further requires the administration to two quantities of polarized gas. The other Grouped inventions to which applicant has asserted share the same technical feature are not related to pulmonary embolism and have divergent method steps. Because the Grouped inventions have different method steps which relate to different modes of operation, functions or effects, it would constitute an undue burden on the examiner to search all of Grouped inventions or any combination thereof, which would encompass many classes/subclasses.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation "the controlled injection rate" in line 1. There is insufficient antecedent basis for this limitation in the claim. The rejection can be obviated by amending the claim to be dependent on claim 3 or amending base claim 8, (i.e., the claim to which claim 9 depends) to be dependent on claim 3.

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The term "small" in claim 20, line 2 (i.e., a small amount) is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (US 5,545,396), by itself, and/or in view of Brasch (US 5,811,076).

Albert discloses a method of screening using MRI imaging which comprises positioning a subject having a pulmonary system (e.g., a human) in an NMR system, injecting a first quantity of polarized <sup>129</sup>Xe, obtaining an NMR signal to yield an MRI and identifying the presence of a blockage. For example, Albert clearly discloses MRI using polarized <sup>129</sup>Xe in a human, see abstract and column 3, lines 64-65 and column 4, lines 35-40. Albert also discloses that the methods are useful for imaging lung tissue, particularly of the vasculature, including various blockages, plaques, etc., which would encompass a pulmonary embolism, see column 12, lines 18-19 and column 17, lines 11-59. Various amounts of gas may be used, see example 3. Albert also discloses that the <sup>129</sup>Xe can be administered via injection and/or inhalation, but that intravenous injection is preferred, wherein the intravenous compositions may contain necessary components (e.g., adjuvants), see column 12, lines 44-55. Also the administration may include multiple injections and controlled rate delivery, see column 4, lines 54. The various other functional limitations in the claims would be inherent characteristics of the methods disclosed by Albert, since Albert administers the same contrast agent, <sup>129</sup>Xe, in the same method, MRI.

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Albert discloses methods of MRI for screening blockages related to lung vasculature which would include pulmonary embolism; however, Albert fails to specifically exemplify such a method and/or recite "pulmonary embolism" as the conditions which are being screened. However, the use of MRI to screen for pulmonary embolism is known in the art, as shown by Brasch.

Brasch discloses methods of MRI and teaches that MRI is specifically useful for screening for pulmonary embolism, see column 1, lines 15-36.

It would have been obvious to one of ordinary skill to screen for pulmonary embolism in the methods disclosed by Albert because Albert teaches an improved method of MRI which provides the advantage of contrast enhanced images of various tissues equivalently, such as, imaging the lungs and various conditions thereof, such as, blockages, etc., which would encompass a pulmonary embolism. One of ordinary skill in the art would have been motivated to employ the methods disclosed by Albert for all the utility taught therein, such as, screening for vascular blockages of the lungs. Additionally, one of ordinary skill in the art would have been motivated to screen for pulmonary embolism, given the teaching of Albert of screening for vascular blockage in lung tissue, since it is known in the art the MRI is especially useful for screening for pulmonary embolism as shown by Brasch.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (US 5,545,396), by itself and/or in view of Brasch (US 5,811,076) as applied to claims 1-19 above, and further in view of Unger (US 6,315,981).

Albert discloses methods of MRI to screen for pulmonary embolism using  $^{129}\text{Xe}$ , as stated above.

Albert fails to disclose that the  $^{129}\text{Xe}$  gas composition contains a mixture of  $\text{CO}_2$  and a surfactant, as well as, expelling large gas bubbles by using gas bubbles less than about 10 microns.

Unger discloses methods of MRI using gas compositions, such as hyperpolarized xenon, see abstract and claim 1. Unger specifically discloses that the addition of a surfactant stabilizes the gas compositions, allowing for increased contrast of the images, see column 12, lines 21+. Unger also teaches that the xenon can be mixed with other gases, such as,  $\text{CO}_2$ , to optimize the gas composition, see column 7, lines 51+. Unger discloses that the methods include expelling larger bubbles to yield

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gasbubbles which are under 12 microns, which encompasses the claimed range, see column 9, lines 65+.

It would have been obvious to one of ordinary skill in the art to modify the methods disclosed by Albert to include the surfactants in the  $^{129}\text{Xe}$  compositions to obtain gasbubbles less than about 10 microns because Albert teaches that various adjuvants may be used for the intravenous compositions and Unger teaches that such contrast agents should include a surfactant to stabilize the compositions to provide extended *in vivo* life of the contrast agent and should be within the claimed size range for safe use thereof. Further, it would have been obvious to one of ordinary skill in the art to modify the compositions used in the methods disclosed by Albert to include Xe mixtures with  $\text{CO}_2$  because Unger teaches that such contrast agents may include mixtures with various gases, including xenon and  $\text{CO}_2$ , to yield gaseous contrast agents which are particularly useful for MRI imaging.

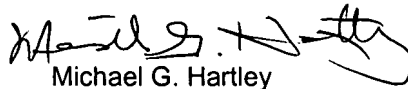
### Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
August 15, 2002